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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,659	08/05/2003	Minako Hijikata	241227US0SRD DIV	5296

22850 7590 05/11/2006

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SWITZER, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,659	HIJIKATA ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 23-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 23-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 August 2003 and 06 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09813031.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/03;8/03;6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copies have been filed in parent Application No. 09/813031, filed on 3/21/01. ***Information Disclosure Statement***

2. The information disclosure statements received 1/5/03, 8/5/03, and 6/1/05 have all been considered. Signed copies of the 1449's are enclosed with this office action. References have been lined through on the 8/5/03 IDS because these citations are incomplete as they do not list a source for the documents, only a title and date.

Specification-Sequence Rules

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s): There are nucleic acid sequences recited in figure 3 that are not identified with a proper SEQ ID NO. The SEQ ID NO should be added to the drawing itself or to the detailed description of the drawings.

In order to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), Applicant must submit, as appropriate, a new CRF and paper copy of the Sequence Listing containing these sequences, in addition to the previously listed sequences, an amendment directing the entry of the Sequence Listing into the specification, an amendment directing the insertion of the SEQ ID NOs into the appropriate pages of the specification and a letter stating that the content of the paper and computer readable copies are the same.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Hijikata et al. (Intervirology, 2000; 43:124-127).

Hijikata et al. teach the identification of a single nucleotide polymorphism in the MxA gene promoter at nucleotide –88 of the promoter, which polymorphism is a G/T polymorphism. Instant SEQ ID NO: 1 is a portion of the MxA gene which comprises the promoter region, with nucleotide 455 of SEQ ID NO: 1 aligning with the nucleotide at position –88 of the promoter as disclosed by Hijikata et al. (see Figure 1 of Hijikata et al. as compared to instant SEQ ID NO: 1 beginning at nucleotides 423). Hijikata et al. teach PCR amplification products comprising portions of this sequence within an agarose gel. An agarose gel is a "base body." Thus, Hijikata et al. provide a base body and a polynucleotide immobilized on said base body.

Regarding claim 1, the polynucleotide immobilized on the base body is a modified polynucleotide of SEQ ID NO: 1 in the sequence listing including several deletions at any position except for the 455th position. For example, the third lane has a 533 nucleotide band that is comprised the nucleic acid comprising the "T" allele. In instant SEQ ID NO: 1, position

455 is a "T" representing the "T" allele. Thus, this molecule which is immobilized on the agarose gel meets the limitations of the polynucleotide set forth in claim 1.

Regarding claim 2, the polynucleotide immobilized in the first lane has a 482 nucleotide band that is comprised of the nucleic acid having the "G" allele. In instant SEQ ID NO: 2, position 455 is a "G," representing the "G" allele. The molecule on the gel would have the "G" of position 455 (-88 of the MxA promoter) in the terminal position due to the cutting of the HhaI enzyme. Thus, this molecule contains the sequence which spans from the 441st to the 455th position of SEQ ID NO: 1. The agarose gel having the immobilized nucleic acid, therefore, meets the limitations of claim 2.

Regarding claim 6, the agarose gel is a "conductive substance."

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

6. Claims 4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuomoto et al. (US 5837819).

Matsuomoto et al. teach a Northern Blot using TAB1 cDNA. The TAB1 cDNA contains the sequence which spans from nucleotides 449-459 of SEQ ID NO: 4, namely nucleotides 1080-1090 of the nucleic acid sequence taught by Matsuomoto et al. as SEQ ID NO: 1 are identical to nucleotides 449-459 of instant SEQ ID NO: 4. Regarding the limitations of claim 4, the solid support on which the blot is carried out is a "base body", and the polynucleotides in the hybridization complex (including the TAB1 cDNA) are immobilized on the base body.

Regarding claim 6, the filter on which the blot is carried out is, to at least some degree, a "conductive substance."

7. Claims 3, 5, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Mittman et al. (US 6821724).

Mittman et al. teach an array comprising a plurality of nucleic acid probes, wherein said plurality comprises over one hundred thousand sequences (see, for example claim 1 and throughout), one of which is their SEQ ID NO: 53621. Such an array comprises a base body (solid support, column 3, line 39) having thereupon a polynucleotide. In this case, instant SEQ ID NO: 53621 taught by Mittman et al. is a polynucleotide comprising a polynucleotide containing the sequence which spans from SEQ ID NO: 449-459 of instant SEQ ID NO: 3. Namely nucleotides 10-20 of SEQ ID NO: 53621 taught by Mittman et al. comprise these nucleotides from instant SEQ ID NO: 3. Regarding claim 5, the length of the polynucleotide immobilized is 25 nucleotides, and regarding claim 6, the surface of the microarray is a "conductive substance" since all substances will be conductive to some degree, and there is no requirement as to how "conductive" the substance should be.

8. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ronni et al. (Journal of Interferon and Cytokine Research 18:773-781 (1998)).

Ronni et al. teach a polyacrylamide gel having immobilized thereupon a probe which comprises a polynucleotide containing the sequence which spans from the 441st to the 455th position of SEQ ID NO: 1, see probe referred to therein as ISRE2, page 774. Thus, regarding claim 1, this is a base body having a polynucleotide immobilized on the base body, since when the polynucleotide binds to a nuclear protein immobilized in the gel, the polynucleotide itself

becomes bound to the gel. Regarding claim 6, the gel taught by Ronni et al. is a conductive substance.

9. Claims 2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al. (Archives of Virology, 1991, as cited in IDS).

Chang et al. teach a Southern blot for the mapping of the human MxA gene, using cosmid pHucos2 which contains the promoter for the human MxA gene. This cosmid comprises a sequence that contains the sequence which spans from nucleotides 449-459 of SEQ ID NO: 2, see for example the sequence beginning at nucleotide 520 of the sequence given in figure 2A of the paper. Regarding the limitations of claim 2, the solid support on which the blot is carried out is a "base body", and the polynucleotides in the hybridization complex (including the cosmid) are immobilized on the base body. Regarding claim 6, the filter on which the blot is carried out is, to at least some degree, a "conductive substance."

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1, 2, 5, 6, 7, 8, 23, 24, 25, 26, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ronni et al. in view of Wang et al. (Analytical Chemistry 1996, 68, 2629-2634).

Ronni et al. provide a promoter analysis of the MxA gene promoter, and teach that this antiviral and immunomodulatory effects of interferons are mediated by this interferon-induced

protein, among other proteins. Ronni et al. provide the sequence of the MxA promoter (which comprises much of instant SEQ ID NO: 1 and SEQ ID NO: 2), specifically teaching that different versions of the promoter have been reported, those which have a "T" at position –88 and those which have a "G" at position –88 (see figure 1). Further, Ronni et al. delineate the putative binding region for interferon-stimulated response elements, noting that one of these elements ends adjacent to the variable –88 position (figure 1). Ronni et al. further demonstrate that this element significantly contributes to interferon responseiveness (p. 777).

Ronni et al. do not provide this element on a DNA chip or carrier which comprises a first and second electrode formed on the base of the body. Ronni et al. do not teach molecules that are between 15 and 30 nucleotides in length and comprising position 455 of SEQ ID NO: 1, which is referred to as position –88 by Ronni et al.

Wang et al. teach sensor electrodes having nucleic acids attached thereupon, and specifically teach the use of such structures for the detection nucleic acids in samples (p. 2630). Thus, these structures are base bodies having immobilized polynucleotides, as set forth in claims 1 and 2.

Regarding claims 5 and 8, Wang et al. exemplify that nucleic acids on the sensors including nucleic acids that are 21 nucleotides in length (p. 2630).

Regarding claim 6, Wang et al. teach base bodies that have polynucleotides attached thereupon, specifically wherein the base body is a electrode which is a conductive substance (see for example, p. 2630, first column).

Regarding claim 7, Wang et al. teach DNA chips which comprise a base body and a first and second electrode formed on the base body, specifically teaching a working electrode

surrounded by a reference and counter electrodes (p. 2630, referred to as carbon paste electrode, reference electrode and platinum wire auxiliary electrode).

Regarding claims 23, Wang teach a reaction section (as the electrode is dipped into target solution) and a marker-detecting apparatus for detecting a marker which measured the marker using chronopotentiometric transduction (p. 2630). Regarding claim 24, it is noted that the marker itself is not required to be a structural component of the claimed apparatus since it is used only to describe the intended use of the reaction section ("for contacting a first polynucleotide immobilized on a base body of said carrier with a sample which contains a second polynucleotide labeled with a marker"). Nonetheless, Wang et al. teach sample teach a label which is accumulated $Co(phen)_3^{3+}$ which is an electrode active substance (p. 2630).

Regarding claim 25, Wang et al. teach Wang et al. teach DNA chips which comprise a base body and a first and second electrode formed on the base body, specifically teaching a working electrode surrounded by a reference and counter electrodes, a voltage application means (electrical contacts stainless steel screw), a reaction section (surface of the electrode), and a measurement section for measuring the signal between the carrier and the counter (p. 2630).

Regarding claim 26, it is noted that the claim recites a method limitation of adding a double strand recognizer to a reaction solution, which is confusing in the context of an apparatus claims. Nonetheless, Wang et al. teach an electro-active double strand recognizer which is accumulated $Co(phen)_3^{3+}$ which generates and electric signal (p. 2630)

Regarding claim 27, Wang et al. teach a carrier for gene detection, as previously discussed, and a buffer solution (p. 2630).

Regarding claim 28, Wang et al. teach a carrier for gene detection, a buffer solution, and double strand recognizer as previously discussed.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the oligonucleotides taught by Ronni et al. so as to have provided fragments of the MxA gene promoter sequence that overlap with the variable position –88 of the MxA gene promoter, and to have provided those on the gene detection electrodes taught by Wang et al. One would have been motivated to study the variable position of the MxA promoter in order to elucidate if this variable position, which is adjacent to the predicted interferon responsive element has any effect on expression of the gene. Further, one would have been motivated to have attached these probes to solid supports to provide products as taught by Wang et al. in order to have provided means for detecting target oligonucleotides in solution and because Wang et al. specifically teach that methods which use these products have advantages including "that they obviate the need for traditional solution assays...eliminate the use of radioisotopes and require shorter hybridization times (p. 2634)." Thus, in view of the teachings of the prior art, the claimed invention is prima facie obvious.

12. Claims 1, 2, 5, 6, 7, 8, 23, 24, 25, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ronni et al. in view of Henkens et al. (US 6391558).

Ronni et al. provide a promoter analysis of the MxA gene promoter, and teach that this antiviral and immunomodulatory effects of interferons are mediated by this interferon-induced protein, among other proteins. Ronni et al. provide the sequence of the MxA promoter (which comprises much of instant SEQ ID NO: 1 and SEQ ID NO: 2), specifically teaching that

different versions of the promoter have been reported, those which have a "T" at position –88 and those which have a "G" at position –88 (see figure 1). Further, Ronni et al. delineate the putative binding region for interferon-stimulated response elements, noting that one of these elements ends adjacent to the variable –88 position (figure 1). Ronni et al. further demonstrate that this element significantly contributes to interferon responseiveness (p. 777).

Ronni et al. do not provide this element on a DNA chip or carrier which comprises a first and second electrode formed on the base of the body. Ronni et al. do not teach molecules that are between 15 and 30 nucleotides in length and comprising position 455 of SEQ ID NO: 1, which is referred to as position –88 by Ronni et al.

Henkens et al. teach sensor electrodes having nucleic acids attached thereupon, and specifically teach the use of such structures for the detection of single nucleotide base pair differences (beginning at Col. 22, section 4.4). Thus, these structures are base bodies having immobilized polynucleotides, as set forth in claims 1 and 2.

Regarding claims 5 and 8, Henkens et al. teach that nucleic acids on the sensors are preferably about 15 to 25 nucleotides in length (Col. 5, lines 33-35).

Regarding claim 6, Henkens et al. teach base bodies that have polynucleotides attached thereupon, specifically wherein the base body is a electrode which is a conductive substance (see for example, Col. 20, lines 45-50).

Regarding claim 7, Henkens et al. teach DNA chips which comprise a base body and a first and second electrode formed on the base body, specifically teaching a working electrode surrounded by a reference and counter electrodes (Col. 20, lines 50-55).

Regarding claims 23, Henkens teach a reaction section (Col. 20, lines 43-56) and a marker-detecting apparatus for detecting the marker (Col. 20, line 64). Regarding claim 24, it is noted that the marker itself is not required to be a structural component of the claimed apparatus since it is used only to describe the intended use of the reaction section ("for contacting a first polynucleotide immobilized on a base body of said carrier with a sample which contains a second polynucleotide labeled with a marker"). Nonetheless, Henkens et al. teach sample polynucleotides labeled with a label (Col. 18, lines 53-62), and provide an example wherein the label is fluorescein, which is both a fluorescent dye and a hapten (Col. 71, line 11).

Regarding claim 25, Henkens et al. teach Henkens et al. teach DNA chips which comprise a base body and a first and second electrode formed on the base body, specifically teaching a working electrode surrounded by a reference and counter electrodes, a voltage application means (electrical contacts), a reaction section (sample well), and a measurement section for measuring the signal between the carrier and the counter (Col. 20, lies 43-56, for example).

Regarding claim 27, Henkens et al. teach a carrier for gene detection, as previously discussed, and a buffer solution (see for example, Col. 34, lines 55-60 describing hybridization buffers).

Regarding claim 28, Henkens et al. teach a carrier for gene detection, as previously discussed, a buffer solution (see for example, Col. 34, lines 55-60 describing hybridization buffers), double strand recognizer, since the entire system is designed to recognize a hybridization event, the entire system functions as a double strand recognizer.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the oligonucleotides taught by Ronni et al. so as to have provided fragments of the MxA gene promoter sequence that overlap with the variable position –88 of the MxA gene promoter, and to have provided those on the gene detection electrodes taught by Henkens et al. One would have been motivated to study the variable position of the MxA promoter in order to elucidate if this variable position, which is adjacent to the predicted interferon responsive element has any effect on expression of the gene. Further, one would have been motivated to have attached these probes to solid supports to provide products as taught by Henkens et al. in order to have provided means for detecting the single base-pair differences within the MxA gene promoter because Henkens et al. specifically teach that methods which use these products have advantages for detecting SNP, including "avoiding expensive equipment, gel electrophoresis, use of radioisotopes, another time consuming methods of traditional molecular biology; inexpensive mass-production for use with multiple samples and probes; small size and less expensive operator training (Col. 23, lines 50-59). Thus, in view of the teachings of the prior art, the claimed invention is prima facie obvious.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-8 and 23-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is written to address the breadth of the polynucleotide immobilized on said base body as set forth in claims 1-4. The rejected claims include these claims and all of the claims that depend from these claims.

The claims are broadly drawn so as to encompass a wide variety of polynucleotides. For example, part (bt) of claim 1 sets forth "a modified polynucleotide derived from (at)" allowing for any number of deletions, substitutions or additions at any positions except for at the 455th postion. Since this claim is broadly drawn to require that the molecule "include" one or several of the recited changes, it can encompass molecules that have greater than one or several changes. The requirement, then, that the changes exclude position 455 is therefore meaningless, because there is no required sequence context for the claimed polynucleotide, and thus, the polynucleotide set forth in the claim simply must include the nucleotide which is at position 455, which in the case of SEQ ID NO: 1 is a "T". Turning to part (ct) of claim 1, the claim is minimally drawn to require only that the molecule "contain" the sequence from nucleotides 441-455 of SEQ ID NO: 1, which is a fifteen base pair sequences which can be surrounded on either side by any potential nucleic acid sequence. Likewise, part (dt) of claim 1 is minimally drawn to require only that the molecule "contain" the sequence from nucleotides 449-459th nucleotides of SEQ ID NO: 1, which is a ten base pair sequences which can be surrounded on either side by any potential nucleic acid sequence. These nucleic acid fragments therefore include fragments of the disclosed MxA promoter, as well as variants of this promoter, but also encompass entirely unrelated gene fragments that have the minimum identity recited with instant SEQ ID NO: 1.

The final recitation in section (et) requires only "a complementary strand" of the polynucleotides previously recited. The use of the indefinite article "a" in the recitation encompasses any nucleic acid which comprises a minimal complementarity of, for example, a single strand. Claims 2, 3, and 4 all have similar recitations regarding instant SEQ ID NO: 2, 3, and 4.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of nucleic acids comprising of SEQ ID NO: 2, 3, and 4, and consisting of fragments of SEQ ID NO: 2, 3, and 4. The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are directed polynucleotides that are defined by only very minimal structure, and as such encompass millions of possible sequences which may or may not be related to the disclosed SEQ ID NO: 1, 2, 3, and 4 in function. The specification only describes particular sequences which are portions of the human MxA gene promoter and fails to teach or describe nucleic acid sequences. Therefore, there is a lack of guidance or teaching regarding structure and function because there are limited examples provided in the specification and because there is additional guidance found in the instant specification regarding other nucleic acid molecules which are within the scope of the claims.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must

be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims, beyond the polynucleotides disclosed as SEQ ID NO: 1-4. The specification does not provide any disclosure of additional MxA gene promoters, of additional variant promoters, or of a wide variety of the vastly claimed genus of nucleic aicds. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention.

Thus, in the application at the time of filing, there is no record or description which would demonstrate conception or written description of all of the nucleic acids encompassed within the instantly claimed invention.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1-8 and 22-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the description of probes (bt), (bg), (ba), and (bc) in claims 1, 2, 3, 4, and 7 the recitation "except for 455th position" is unclear because it is not clear if this language means that since the base at position 455 in SEQ ID NO: 1, for example is "T" then what must be

unchanged, in any context or if some context around the "T" is required. If applicant intends the latter, it is not clear how one could identify the 455th position if any number of nucleotides on either side of the position can be modified or deleted or nucleotides can be added on, as then this position might not be 455, and the nucleotide context might be different. Furthermore, it is unclear what applicant intends when they recite "a complementary strand" since it is not clear if this language means a sequence or subsequence with any level of complementarity (i.e. as little as one or two nucleotides complementary to SEQ ID NO: 1) or if applicant intends that this recitation encompass "the complement" of SEQ ID NO: 1 in its entirety.

Claim 5 is confusing when it recites "the length of the polynucleotide to be immobilized on said base body" because the independent claims do not require a polynucleotide which will be immobilized in the future (to be immobilized) but instead require that a polynucleotide is immobilized on the base body to meet the limitations of the claims. Therefore, when applicant refers to the polynucleotide "to be immobilized" proper antecedent basis is not present in the claims.

Claim 6 is confusing because it recites a method step "is used as an electrode" and it is not clear how this method step is intended to limit the claimed product.

Claim 8 is confusing when it recites "the length of the polynucleotide to be immobilized on said base body" because the independent claim does not require a polynucleotide which will be immobilized in the future (to be immobilized) but instead require that a polynucleotide is immobilized on the base body to meet the limitations of the claims. Therefore, when applicant refers to the polynucleotide "to be immobilized" proper antecedent basis is not present in the claims.

Claim 23 is confusing because it recites the method step "putting the first and second polynucleotides under hybridization reaction conditions" and it is not clear how this method step is intended to limit the claimed product.

Claim 24 is confusing because it is not clear how the descriptions of the marker is intended to limit claim 23, since claim 23 does not actually require the presence of the marker, but only requires a carrier, a reaction section and a marker-detecting apparatus. The reference to the marker on the second polynucleotide is part of the intended use language set forth in the claims.

Claim 26 is confusing because it recites the method step that a double strand recognizer "is added in said reaction section" but it is not clear what product limitation is intended for the claimed apparatus by this method recitation.

Double Patenting

17. Claims 1, 5-8 and 22-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of US Patent 6783935 in view of Henkens et al. or Wang et al.

The claims of the US Patent are drawn to a polynucleotide comprises SEQ ID NO: 1 of that application, which is identical to SEQ ID NO: 1 of this application. The claims of the '935 application do not provide this polynucleotide on a base body or electrode or the specific constructs set forth in the instant claims. The teachings of Henkens and Wang, discussed earlier in this office action provide constructs for detection of nucleic acids which comprise base bodies, electrodes and the elements of the constructs set forth in the instant application. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention

was made to have modified the nucleic acids claimed in the '935 patent so as to have included them on base bodies, electrodes and the specific constructs claimed in this application in order to provide products as set forth in Henkens et al. and/or Wang et al., as discussed previously in this office action.

18. Claims 1-8 and 22-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-25, 32, and 33 of copending Application No. 10/070415 in view of Henkens et al. or Wang et al.

The claims of the application teach a substrate (base body) including immobilized thereupon fragments of the human MxA promoter, which are identical to instant SEQ ID NO: 1-4 and to the polynucleotides set forth in instant claims 1-4. See claim 23, for example, reciting a second probe which comprises their SEQ ID NO: 17, 18, 19, or 20, or fragments thereof, which sequences are identical to instant SEQ ID NO: 1-4. The claims of the '935 application do not provide this polynucleotide on a base body or electrode or the specific constructs set forth in the instant claims. The teachings of Henkens and Wang, discussed earlier in this office action provide constructs for detection of nucleic acids which comprise base bodies, electrodes and the elements of the constructs set forth in the instant application. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the nucleic acids claimed in the '415 application so as to have included them on base bodies, electrodes and the specific constructs claimed in this application in order to provide products as set forth in Henkens et al. and/or Wang et al., as discussed previously in this office action.

This is a provisional obviousness-type double patenting rejection.

Conclusion

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Thursday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

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Juliet C. Switzer
Primary Examiner
Art Unit 1634

May 9, 2006